

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 1 and 10-19 were previously pending in this application. By this amendment, Applicant is canceling claims 12, 13 and 17, without prejudice or disclaimer. Claim 1 has been amended to incorporate the features of claims 12, 13 and 17. Claim 18 has been amended to maintain appropriate claim dependency due to the cancellation of claim 12 and clarify the claim language. As a result, claims 1, 10-11, 14-16, and 18-19 are pending for examination with claim 1 being an independent claim. No new matter has been added.

### **Rejections Under 35 U.S.C. § 102**

The Examiner rejected claims 1, 10, 12-14 and 19 under 35 U.S.C. § 102(b) as being anticipated by Berman et al. (1998; *Pain* 75:199-207). Applicant respectfully requests reconsideration.

The Examiner alleges that the paper by Berman et al. teaches each and every element of claims 1, 10, 12-14 and 19. Claim 1 has now been amended to include the limitation of previously pending claim 17, namely that the medicament is provided in a form capable of delivering a mean daily dose of less than 37.5 mg of THC. Berman contains no disclosure or teaching with regard to the dosage of cannabis (let alone that of THC and/or CBD) to be used in the treatment of neuropathic pain caused by brachial plexus avulsion. This fact is acknowledged by the Examiner on page 4 of the Office Action. Therefore, claim 1 and its dependent claims are clearly novel over the cited prior art documents.

Accordingly, withdrawal of this rejection is respectfully requested.

**Rejections Under 35 U.S.C. § 103**

The Examiner rejected claims 11 and 15-18 under 35 U.S.C. § 103(a) as being unpatentable over Berman et al. (1998) as applied to claims 1, 10, 12-14 and 19, and further in view of Maurer et al. (1990; European Archives of Psychiatry and Clinical Neuroscience, 240:1-4). Applicant respectfully requests reconsideration.

The Examiner considers claims 11 and 15-18 to be obvious in view of the combination of Berman et al. and Maurer et al. The Examiner alleges that the symptomology found in the patient described by Maurer et al. is similar to that found in patients suffering from brachial plexus avulsion as taught by Berman et al.

However, the patient in Maurer was a cancer patient who experienced loss of movement in the arms and spasticity in the legs following surgery to remove a tumour. The patient did not report the “characteristic constant crushing and intermittent shooting pain” associated with brachial plexus avulsion, but rather reported “painful paraesthesias and spasticity in the legs.” Furthermore, the passage of Maurer highlighted by the Examiner (Neurological examination, page 2) reports that the patient’s cranial nerves were intact. By contrast, brachial plexus avulsion is, by definition, a condition associated with nerve lesions. Thus, it is difficult to see how the skilled person would be motivated or have any reason to combine Maurer and Berman.

In any case, the combination of Maurer and Berman do not contain any teaching which would direct the skilled person to use the recited dose of THC in the treatment of brachial plexus avulsion. As reported by Berman, and as is stated in the current application, pain associated with brachial plexus avulsion is known to be particularly severe. There is no suggestion in either Berman or Maurer that low doses of THC could be successful in treating this severe pain. The obvious treatment option would be to give a larger dose of THC to increase the relief of pain, yet the surprising finding from the study described in the present application was that a lower dose was

effective. Thus Applicant has demonstrated unexpected results that support a finding of nonobviousness.

In view of the foregoing, Applicant submits that the cited matter of the current claims is not obvious from the combination of cited documents. Accordingly, withdrawal of this rejection is respectfully requested.

### **CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,  
*Catherine Symonds et al., Applicant(s)*

By: /John R. Van Amsterdam/  
John R. Van Amsterdam  
Reg. No. 40,212  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Date: April 25, 2008  
**X4/28/08X**